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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/407,806	09/28/1999	DENNIS MURPHY	DIVER1120-1	3254

20985 7590 11/17/2003

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EXAMINER	
STEADMAN, DAVID J	
ART UNIT	**PAPER NUMBER**
1652	33

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/407,806	MURPHY ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,13,14,17-25,27-30,34,36,37 and 42-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,13,14,17-25,27-30,34,36,37 and 42-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Applic tion

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 18, 2003, has been entered.

[2] Claims 1-9, 13-14, 17-25, 27-30, 34, 36-37, and 42-67 are pending.

[3] Applicants' cancellation of claims 26, 31-33, 35, and 38-44, amendment to claims 1-3; 5-8, 13-14, 19, 21-22, 24-25, 27-30, 34, 36-37, and 42-45, and addition of claims 46-67 in Paper No. 32, filed August 18, 2003, is acknowledged. The listing of claims as set forth in Paper No. 32 replaces all prior versions.

[4] Applicants' amendment to the specification in Paper No. 32 is acknowledged.

[5] It is noted that applicants request entry of an amended drawing enclosed with Paper No. 32 (see page 12 of Paper No.32). However, the examiner can find no substitute drawing filed with Paper No. 32.

[6] Applicant's arguments filed in Paper No. 32 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[7] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Specification/Informalities

[8] Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and/or 121 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 120 and/or 121 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

[9] The amendment to the sequence listing and Figure 1 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicants state that upon re-sequencing of the plasmid 18GC, three nucleotide discrepancies have been noted, which did not alter the encoded sequence of SEQ ID

NO:4 (see page 14 of Paper No. 32). Applicants have submitted a substitute sequence listing and substitute Figure 1 to provide the new nucleotide sequence of SEQ ID NO:3 per the re-sequenced 18GC. However, there is no support for this new sequence of SEQ ID NO:3 in the figures, specification, or claims as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

[10] Claim 1 is objected to because of the following informalities: the term "comprising a a polynucleotide" in lines 2-3 is grammatically incorrect and should be replaced with, for example, "comprising a polynucleotide". Appropriate correction is required.

[11] Claim 27 is objected to because of the following informalities: the term "wherein the polynucleotides" in line 2 is grammatically incorrect and should be replaced with, for example, "wherein the polynucleotide". Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

[12] Claims 2-4, 8, 17-22, 28, and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claims 2 (claims 4 and 17-19 dependent therefrom), 3, 21, 22, and 61 are confusing in the recitation of "polynucleotide comprises a DNA" in claim 2, "polynucleotide comprises an RNA" in claim 3, "vector comprises a plasmid" in

claim 21, "vector comprises an expression vector" in claim 22, and "DNA comprises an antisense sequence" in claim 61. From the claims, it is unclear as to whether the term "comprises" is meant to be interpreted as "is" or as "encompasses". In the interest of advancing prosecution, the examiner has interpreted the term as "is" and the claims have been examined accordingly.

[b] Claims 8, 20, 28, recite the limitations "said DNA" (claim 8), "the DNA" (claim 20), "the wash step" (claim 28), . There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 112, First Paragraph

[13] Claims 24, 25, 27-30, 34, 36-37, 42-45, 51-56, and 62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a genus of polynucleotides comprising fragments of a polynucleotide encoding SEQ ID NO:4 or fragments of a variant of a polynucleotide encoding SEQ ID NO:4. For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics

coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single representative species of the genus of claimed polynucleotides, i.e., SEQ ID NO:3 encoding the polypeptide of SEQ ID NO:4. The specification fails to describe any additional representative species of the claimed genus of polynucleotides. While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it is also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus". In the instant case, the recited genus encompasses species having widely variant structures and/or functions – including mutants, allelic variants, and/or genomic DNA. As such, the disclosure of the single representative species, i.e., SEQ ID NO:3, is insufficient to be representative of the attributes and features of *all* species encompassed by the recited genus. Given the lack of description of a representative number of species, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

In the advisory action of Paper No. 29, the examiner contrasted Example 14 of the Revised Written Description Guidelines (The Guidelines), which presents claims that are adequately described, and claims 24, 25, and 27-45, which did not meet the written description. In addressing the examiner's statements of Paper No. 29, applicants argue (beginning at page 18 of Paper No. 32) specific hybridization conditions as a limitation in a claim are analogous to sequence identity as a physico-chemical property limitation. The examiner acknowledges applicants' arguments and notes that, while hybridization language can be included as a limitation in a claim, in the claims as previously presented, the specific hybridization conditions were absent from the claims. As such, the examiner was unable to determine the scope of polynucleotide structures encompassed by the claims and consequently, the species of polynucleotides encompassed by the genus of the claims.

Beginning at the bottom of page 19 of Paper No. 32, applicants argue that claims reciting less than 95% sequence identity and claims reciting stringent hybridization language have been issued in recent patents. Applicant's argument is not found persuasive.

Applicants have mischaracterized the examiner's position. The examiner has never required or suggested that applicant amend their claims to recite "95% sequence identity" as a limitation. Instead, the rejection has been made and maintained as the specification fails to adequately describe a *representative number of species* of the claimed polynucleotides, which encompass species that are widely variant in both structure and function. In regards to applicants' citation of issued patents, applicants are

respectfully reminded that each patent application is examined on its own merits. A determination of whether a given polynucleotide claimed in an issued US patent would require a detailed review of the record of each individual case.

Applicants argue (beginning at the top of page 20 of Paper No. 32) the claimed invention complies with the written description requirements as set forth by Federal Circuit case law. Applicants argue that when a disclosed function of an enzyme encoded by a polynucleotide is correlated with a known structure and a physical property, the claimed sequences are adequately described. Applicant's argument is not found persuasive.

In this case, the specification fails to describe the genus of claimed polynucleotides, which encompass species having widely variant structures AND functions. Contrary to applicants' assertions, the genus of polynucleotides is not limited by structural AND functional features. For example, claim 24 is drawn to a polynucleotide that hybridizes to a polynucleotide encoding a polypeptide having SEQ ID NO:4, wherein the polypeptide has alpha-galactosidase activity. While the polynucleotide is limited to structures that would meet the hybridization limitation, the claimed polynucleotide IS NOT limited to any function. Thus, the claimed polynucleotide itself can have any function and can encode a polypeptide having any function – a genus of polynucleotides that encompass widely variant species. Also, the genus of polynucleotides of claim 29 is structurally limited to comprising "at least 12 contiguous nucleotides" of the polynucleotide of claim 1 or 24. In this case, the structures AND functions of species encompassed by the claim are widely variant. Further, while claim

34 is drawn to a nucleic acid consisting of at least 12 nucleotides of a polynucleotide encoding SEQ ID NO:4, the genus encompasses species having widely variant structures and functions, including genomic DNA. In summary, the single representative species of SEQ ID NO:3 fails to describe claimed genus of claimed nucleic acids.

[14] Claims 1-3, 5-9, 13-14, 17-25, 27-30, 34, 36-37, 42-62, and 64-67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding SEQ ID NO:4, does not reasonably provide enablement for *all* polynucleotide variants as encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

- The claims are overly broad in scope: The claims are so broad as to encompass a vast number of variants of a polynucleotide encoding SEQ ID NO:4. The broad scope of the claimed nucleic acids is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acids broadly encompassed by the claims. In this case the disclosure is limited to a polynucleotide encoding SEQ ID NO:4.

- The lack of guidance and working examples: The specification provides only a single working example of the claimed nucleic acids, i.e., SEQ ID NO:3. This single working example fails to provide the necessary guidance for making and using the entire scope of claimed nucleic acids. Regarding those claims reciting structural and functional limitations (*e.g.,* claims 1-3, 5-9, 13-14, 17-23, 46-50, 57-61, 64-67), while it is noted that the specification provides methods for screening for alpha-galactosidase activity (see, *e.g.*, pages 18-19 of the specification), such guidance is insufficient to enable a skilled artisan to make all claimed nucleic acids broadly encompassed by the claims. In this case, the specification merely provides a starting point for additional research providing no more than a plan or invitation for those of skill in the art to experiment in order to generate the entire scope of recited nucleic acids. See *University of Rochester v. G.D. Searle & Co. Inc.,* W.D. N.Y., No. 00-CV-6161L, 3/5/03.

- The high degree of unpredictability in the art: The nucleotide sequence of an encoding nucleic acid determines the corresponding encoded protein's structural and functional properties. Predictability of which changes can be tolerated in an encoded protein's amino acid sequence and obtain the desired activity requires a knowledge of

and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The positions within an encoding nucleic acid's sequence where modifications can be made with a reasonable expectation of success in obtaining an encoded polypeptide having the desired activity/utility are limited in any protein and the result of such modifications is highly unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. In this case, the necessary guidance has not been provided in the specification as explained in detail above. Thus, a skilled artisan would recognize the high degree of unpredictability that the entire scope of polynucleotides would encode a polypeptide having the desired activity. The ability to assign a protein's function based on similarities to other proteins, even those that are naturally occurring, is *highly* unpredictable.

- The state of the prior art supports the high degree of unpredictability: The state of the art provides evidence for the high degree of unpredictability in altering a polynucleotide sequence with an expectation that the encoded polypeptide will maintain the desired activity/utility. For example, Branden et al. ("Introduction to Protein Structure", Garland Publishing Inc., New York, 1991) teach "[p]rotein engineers frequently have been surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes" and "[t]he often surprising results of such experiments reveal how little we know about the rules of

protein stability... ...they also serve to emphasize how difficult it is to design *de novo* stable proteins with specific functions" (page 247). While it is acknowledged that this reference was published in 1991, to date there is no general or specific guidance in the prior art for reasonably predicting the effects of even a *single* amino acid mutation on a protein. Such mutations may even completely alter a protein's activity. As a representative example, Witkowski et al. (*Biochemistry* 38:11643-11650) teaches that a single amino acid substitution results in conversion of the parent polypeptide's activity from a beta-ketoacyl synthase to a malonyl decarboxylase (see e.g., Table 1, page 11647). Thus, the prior art acknowledges the unpredictability of altering a protein-encoding sequence with an expectation of obtaining a protein having a desired function and discloses that even a single substitution in a polypeptide's amino acid sequence may completely alter the function of a polypeptide.

- The amount of experimentation required is undue: While methods of generating variants of a given polynucleotide, e.g., mutagenesis, and methods of isolating homologous polynucleotides, e.g., hybridization, are known, it is not routine in the art to screen for *all* polynucleotides having a substantial number of substitutions or modifications as encompassed by the instant claims. Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

It is noted that this rejection has been applied to claims not rejected in the last Office action. Based on the lack of guidance provided in the specification as described above, the examiner has determined that the specification fails to fully enable the full scope of these claims.

Applicants argue (beginning at the middle of page 20 of Paper No. 32) that undue experimentation is not required to make and use the full scope of the claimed invention. Applicants assert guidance as to how much experimentation may be required without being undue is addressed in *Hybritech Incorporated v. Monoclonal Antibodies, Inc.* (CAFC) 231 USPQ 81 (9/19/1986). Applicants argue that because those of skill in the art are prepared to screen a large number of negatives to find a sample having the desired properties, this screening is not undue experimentation. Applicants argue that analogous to *Hybritech,* applicants argue that many samples may need to be screened to make the full scope of claimed nucleic acids. Applicants argue screening protocols were routine at the time of the invention and the level of skill in the art was high.

Applicants argue the specification sets forth methods for determining sequence identity and hybridization conditions. Applicants argue that the specification need not disclose that which is well known. Applicants conclude that the specification provided sufficient guidance for making and using the full scope of claimed nucleic acids. Applicant's argument is not found persuasive.

As stated above, while it is noted that the specification provides methods for screening for alpha-galactosidase activity (see, *e.g.*, pages 18-19 of the specification), such guidance is insufficient to enable a skilled artisan to make all claimed nucleic acids broadly encompassed by the claims. While the screening required in *Hybritech* may have been considered routine, it is not routine in the art to screen for *all* polynucleotides having a substantial number of substitutions and modifications as encompassed by the instant claims. There is no evidence of record to indicate or even suggest that the sequence of SEQ ID NO:3 or 4 were so well-characterized and/or well-known in the art such that a skilled artisan could have reasonably predicted the effects of varying the sequence of SEQ ID NO:3 or 4 with an expectation of obtaining a nucleic acid having the desired characteristics. The instant case is analogous to *University of Rochester v. G.D. Searle & Co. Inc.,* W.D. N.Y., No. 00-CV-6161L, 3/5/03. The court stated, "although the '850 patent describes an assay for determining whether a given compound possesses certain desired characteristics, and identifies some broad categories of compounds that *might* work, these descriptions, without more precise guidelines, amount to little more than 'a starting point, a direction for further research'". In the instant case, the specification provides an assay for determining those nucleic

acids that encode polypeptides having alpha-galactosidase activity (pages 18-19 of the specification). The specification further asserts that variants of SEQ ID NO:3 encoding polypeptides having alpha-galactosidase activity can be generated, without providing guidance or the necessary information for altering SEQ ID NO:3 with an expectation of obtaining a nucleic acid encoding a polypeptide having alpha-galactosidase activity. These nucleic acids are a broad category of compounds that *might* work, i.e., might have alpha-galactosidase activity. In fact, without such guidance it is possible that even a single mutation in the coding sequence may disrupt alpha-galactosidase activity. Instead, applicants assert that, with a large amount of further experimentation, i.e., screening to identify those desired nucleic acids, one of skill can make the full scope of claimed nucleic acids. However, for those reasons stated above, this would clearly require undue experimentation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

[15] Claims 1-9, 13-14, 17-25, 27-30, 34, 36-37, and 42-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 10-16, 22-31, and 37-64 of copending Application No. 10/112,331 (hereafter referred to as "Application '331"). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application and the claims of Application '331 are both directed to an isolated or recombinant nucleic acid encoding a polypeptide having alpha-galactosidase activity, fragments and variants thereof, complements thereof, a vector comprising said nucleic acid, a host cell containing said vector, and a method of making a polypeptide. The claims differ in that the claims of Application '331 recite SEQ ID NO:3, while the claims of the instant application recite nucleic acids encoding SEQ ID NO:4. It should be noted that SEQ ID NO:3 of both applications encodes SEQ ID NO:4. The claims of the instant application cannot be considered to be patentably distinct over the claims of Application '331 when there is a specifically recited embodiment in Application '331 that would anticipate claims the claims of the instant application. This is a provisional obviousness-

type double patenting rejection because the conflicting claims have not in fact been patented.

[16] Claim 8 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 133-137 of copending Application No. 09/886,400 (hereafter referred to as "Application '400"). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application and the claims of Application '400 are both directed to a process or method of making a polypeptide. The claims differ in that claims 133-134 of Application '400 recite a nucleic acid encoding an alpha-galactosidase that is at least 50% identical to SEQ ID NO:4, while claim 8 of the instant application recites a nucleic acids having at least 70% identity to a polynucleotide encoding SEQ ID NO:4. The claims of the instant application cannot be considered to be patentably distinct over the claims of Application '400 when there is a specifically recited embodiment in Application '400 that would anticipate claims the claims of the instant application. Moreover, it would have been obvious to one of ordinary skill in the art to use a prokaryotic or eukaryotic host cell using a promoter linked to the nucleic acid in the method of claim 8 of the

instant application and claims 135-137 of Application '400 would have been obvious to one of ordinary skill in the art at the time of the instant invention. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

[17] Claim 8 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of copending Application No. 10/112,357 (hereafter referred to as "Application '357"). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application and the claim of Application '357 are both directed to a process or method of making a polypeptide. The claims differ in that claim 29 of Application '357 recites a nucleic acid having: at least 50% sequence identity to at least 20 consecutive residues of SEQ ID NO:3, wherein the nucleic acid encodes an alpha-galactosidase or at least 50% sequence identity to at least 20 consecutive residues of a nucleic acid encoding SEQ ID NO:4, while claim 8 of the instant application recites a nucleic acids having at least 70% identity to a polynucleotide encoding SEQ ID NO:4. The claims of the instant application cannot be considered to be patentably distinct over

the claims of Application '357 when there is a specifically recited embodiment in Application '357 that would anticipate claims the claims of the instant application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

[18] Status of the claims:

- Claims 1-9, 13-14, 17-25, 27-30, 34, 36-37, and 42-67 are pending.
- Claims 1-9, 13-14, 17-25, 27-30, 34, 36-37, and 42-67 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

11-14-03

DAVID STEADMAN
PATENT EXAMINER